PATENT

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Application No.:		10/659,490	Confirmation No.: 3452
Applicant	:	Robert B. DeVries	
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TC/A.U.	:	3731	
Examiner	:	Lang, Amy T.	
Title	:	COMPOSITE MEDICAL DEVICES	
Docket No.	:	1001.1602101	
Customer No.	:	28075	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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By JoAnn Lindman

Dear Sir:

Appellant respectfully requests a Pre-Appeal Brief Review of the pending application. A Notice of Appeal is filed herewith.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

Appellants have carefully reviewed the Final Office Action of November 30, 2009 and the Advisory Action of February 18, 2010. Currently, claims 1-69 are pending in the application of which claims 11-64 have been withdrawn. Claims 1-10 and 65-69 have been rejected by the Examiner. Favorable consideration of the claims is respectfully requested.

Claims 1-4, 6-10, and 65 were rejected under 35 U.S.C. 102(b) as anticipated by Tomonto (U.S. Patent No. 6,425,855). Appellants respectfully traverse the rejection for at least the reason that Tomonto does not expressly or inherently describe each and every element as set forth in the claim. Claim 5 was rejected under 35 U.S.C. 103(a) as obvious over Tomonto in view of Moore (U.S. Published Patent Application No. 2004/0024444). Appellants respectfully traverse the rejection for at least the reason that claim 5 depends from nonobvious independent claim 1 and therefore is also nonobvious.

Two primary issues remain to be resolved. The first is whether a portion of an outermost layer of a tubular element comprising three layers would be interpreted by one of ordinary skill in the art to disclose that the outermost layer "surrounds" the central layer to form a composite member having a solid cross section. The second issue relates to the inherency of properties attributed to the materials disclosed by Tomonto.

Pending independent claim 1 recites in part:

> "a first composite elongated member formed from an outer member comprising a first material and an inner member comprising a second material different from the first material, the outer member surrounding and encasing the inner member, wherein the second material is more elastic than the first material" and further
> "wherein said first composite elongated member has a solid cross-section"

The composite elongated member is a solid wire forming a leg of a vena cava filter having the cross-section indicated, for example, in Figs. 3 and 4 reproduced below for convenience:

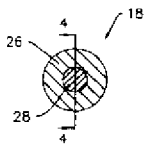


FIG. 3

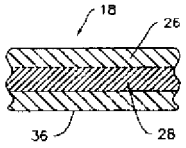
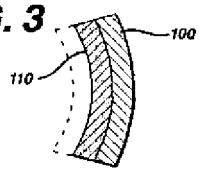


FIG. 4

The cross-section of Tomonto, believed to most nearly correspond to the figures above, resembles modified Fig. 3 of Tomonto reproduced below. Because the Examiner appears to be relying upon an embodiment of Tomonto not illustrated, an optional innermost third layer of the stent of Tomonto has been added as indicated in phantom.

FIG. 3



The section of the stent strut illustrated in Fig. 3 of Tomonto remains when slots are cut through the wall of a tubular blank. In some cross-sections of a strut of Tomonto, both layers 100 and 110 are present while in other portions along length of the strut outer layer 100 is subsequently removed to leave only layer 110. It is Appellants' position that layer 100 may only be described as adjacent to one of three sides of layer 110 in the solid composite strut disclosed by Tomonto. The Examiner appears to have asserted two positions. The first is that, in the stent as a whole, the layer 100, when present, lies everywhere radially outward of layer 110 and so continuously "surrounds" or encircles it. It is Appellants' belief that this interpretation is in error for a number of reasons including the observation that layer 110 has significantly greater area than any of the three expandable grafts 20, 30, 40 affixed to its outer surface. Layer 110 has an area which is equal to over half of the exposed area (inside and outside surfaces of the stents) of any of the illustrated stent embodiments, while the area of each of the remaining portions of layer 100 of the stent (one of three grafts disposed only on the outer surface; each less than one third of the length of the stent) comprise less than one sixth of the exposed area of the stent. Further, a transverse line through the stent body passing through the axis of the body would encounter, in sequence, 100/110/air/110/100 and so a body in which layer 100 "surrounds" a small portion of layer 110 would be hollow and not be solid as recited in claim 1.

The Examiner has also presented an alternate interpretation of Tomonto in which a third layer is present as described at col. 4, lines 50-53: "The stent could have more than two layers and still possess all the advantages of the present invention."

Cutting the stent from a three layer tubular element would apparently create a strut having three layers as illustrated in modified Fig. 3 of Tomonto above which would now result in a solid composite elongate member, but one in which layer 110 of the strut is fully exposed on two of the four sides and still only in contact with layer 100 on 1 of four sides. The Examiner has characterized this arrangement as: "the outer layer is

external to and directly attached to the inner layer on multiple sides so that the outer layer clearly surrounds the inner layer". Appellants respectfully disagree. Note that there is no continuity between the outer layer 100 and any inner layer which may be present and thus layer 100 does not surround layer 110 in a solid strut of the stent of Tomonto.

For at least this reason, Tomonto does not anticipate each and every element of claim 1 and the rejection should be overruled.

Claim 1 also recites: "wherein the second material is more elastic than the first material" where the outer member comprises a first material and the inner member comprises a second material different from the first material.

Here, the issue is whether Tomonto discloses that a second inner material is more elastic than the first outer material. As noted above, Tomonto does not appear to disclose first outer and second inner materials in the sense required by claim 1 and thus cannot provide a basis for the necessary determination. As also discussed, the Examiner has proceeded on the erroneous assumption that the outermost layer of the stent of Tomonto corresponds to the first material and that the significantly larger (following etching to remove portions of the outer layer following cutting of the tube) layer 110 corresponds to the second material. Tomonto characterizes the two materials generically as "plastically deformable" and "superelastic" respectively and suggests that a stainless steel would be suitable for layer 100 and that a superelastic Nitinol would be suitable for layer 110. No properties are disclosed for the materials other than "plastically deformable" and "superelastic". No grade of stainless steel is specified. No Nitinol or nitinol-type composition or process history is specified and thus the disclosure does not inherently disclose that the material 110 of Tomonto is more elastic than material 100.

The Examiner has made a number of assertions regarding the relative mechanical properties of stainless steel and Nitinol. Initially, it should be noted that neither "stainless steel" nor "Nitinol" would be understood by one of ordinary skill in the art to specify a single chemical composition and further one of ordinary skill in the art would appreciate that the mechanical properties of any given composition of those materials depend upon both the mechanical and thermal history to which the sample has been subjected. This is especially true of Nitinol where the art relies upon processing to greatly alter the mechanical properties of an article fabricated therefrom. Further,

depending upon the conditions of use, stainless steel may be characterized as "elastic" at small deflections and Nitinol may be characterized as "plastically deformable".

In the Advisory Action, the Examiner turns to a secondary reference, (Mansmann et al.; USPPA 2009/0132047 which claims priority to a provisional application filed November 30, 2004, 1 year, 2 months and 20 days after the filing of the pending application) to show that Nitinol alloys are more flexible and elastic than stainless steel. Aside from the inappropriate date of the reference, Mansmann only states that "various nitinol-type alloys are much more flexible and elastic than stainless steel". This would appear to provide insufficient basis to assert that all Nitinol alloys are, under all conditions, inherently more elastic than all stainless steels. For at least this reason, Tomonto does not anticipate each and every element of claim 1 and the rejection should be overruled.

Moore is asserted to provide an outer polymeric coating not found in claim 1 and so does not overcome the deficiencies of Tomonto as applied to independent claim 1.

Claims 2-4, 6-10, and 65, which depend from nonobvious independent claim 1, also are believed to be nonobvious and Appellants respectfully request that the rejections be overruled.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: March 24, 2010

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